Complete Summary

GUIDELINE TITLE

Medical management of adults with osteoarthritis.

BIBLIOGRAPHIC SOURCE(S)

Michigan Quality Improvement Consortium. Medical management of adults with osteoarthritis. Southfield (MI): Michigan Quality Improvement Consortium; 2005 Aug. 1 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Michigan Quality Improvement Consortium. Medical management of adults with osteoarthritis. Southfield (MI): Michigan Quality Improvement Consortium; 2003 Aug. 1 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, the U.S. Food and Drug Administration (FDA) asked manufacturers of non-prescription (over the counter [OTC]) non-steroidal anti-inflammatory drugs (NSAIDs) to revise their labeling to include more specific information about potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drugs. See the <u>FDA</u> Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all NSAIDs make labeling changes to their products. FDA recommended proposed labeling for both the prescription and OTC NSAIDs and a medication guide for the entire class of prescription products. See the <u>FDA Web site</u> for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Osteoarthritis

GUIDELINE CATEGORY

Evaluation Management Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Rheumatology

INTENDED USERS

Advanced Practice Nurses Health Plans Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To achieve significant, measurable improvements in the management of osteoarthritis through the development and implementation of common evidence-based clinical practice guidelines
- To design concise guidelines that are focused on key management components of osteoarthritis to improve outcomes

TARGET POPULATION

Adults 18 years or older with clinical suspicion or confirmed diagnosis of osteoarthritis

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

Detailed history, physical examination, and assessment of gastrointestinal (GI) risk

Management/Treatment

Non-Pharmacologic Modalities

- 1. Education and counseling regarding weight reduction, joint protection, and energy conservation
- 2. Range-of-motion, aerobic, and muscle strengthening exercises
- 3. Physical therapy and occupational therapy for patients with functional limitations
- 4. Assistive devices for ambulation and activities of daily living
- 5. Appropriate footwear, orthotics
- 6. Self-management
- 7. Complementary alternative medicine

Pharmacologic Therapy

- 1. Acetaminophen
- Other pharmacologic agents such as nonacetylated salicylate, tramadol, opioids, intra-articular glucocorticoids or hyaluronate, topical capsaicin or methyl salicylate
- 3. Non-steroidal anti-inflammatory drugs (NSAIDs) with addition of an antacid, H₂ blocker, or proton pump inhibitor (PPI) if GI symptoms develop

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Michigan Quality Improvement Consortium (MQIC) project leader conducts a search of current literature in support of the guideline topic. Computer database searches are used to identify published studies and existing protocols and/or clinical practice guidelines on the selected topic. A database such as MEDLINE and two to three other databases are used.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for the Most Significant Recommendation

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational studies
- D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Using the health plan guideline summaries and information obtained from the literature search, the Michigan Quality Improvement Consortium (MQIC) director and/or project leader prepare a draft guideline for review by the MQIC Medical Directors.

The draft guideline and health plan guideline summaries are distributed to the MQIC Medical Directors for review and discussion at their next committee meeting.

The review/revision cycle may be conducted over several meetings before consensus is reached. Each version of the draft guideline is distributed to the MQIC Medical Directors, Measurement, and Implementation committee members for review and comments. All feedback received is distributed to the entire membership.

Once the MQIC Medical Directors achieve consensus on the draft guideline, it is considered approved for external distribution to practitioners with review and comments requested.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Once the Michigan Quality Improvement Consortium (MQIC) Medical Directors achieve consensus on the draft guideline, it is considered approved for external distribution to practitioners with review and comments requested.

The MQIC director also forwards the approved guideline draft to presidents of the appropriate state medical specialty societies for their input. All feedback received from external reviews is presented for discussion at the next MQIC Medical Directors Committee meeting. In addition, physicians are invited to attend the committee meeting to present their comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The level of evidence grades (A-D) are provided for the most significant recommendations and are defined at the end of the "Major Recommendations" field.

Initial Evaluation

- Detailed history (aspirin use, pain control with over-the-counter medications, activity tolerance and limitations)
- Physical examination
- Assess gastrointestinal (GI) risk:
 - History of ulcer disease and/or GI bleeding
 - High dose, chronic, or multiple non-steroidal anti-inflammatory drugs (NSAIDs) including aspirin
 - Concomitant use of corticosteroids and/or warfarin [A]
 - Age >60 yrs

Nonpharmacologic Modalities

Treatment plan should include:

- Education and counseling regarding weight reduction, joint protection, and energy conservation
- Range-of-motion [B], aerobic, and muscle strengthening exercises
- Physical therapy and occupational therapy for patients with functional limitations
- Assistive devices for ambulation and activities of daily living
- Appropriate footwear, orthotics (e.g., wedged insoles)

- Self-management resources (e.g., American Arthritis Foundation self help course and book)
- Complementary alternative medicine (e.g., glucosamine)

Pharmacologic Therapy

Non-NSAID Analgesics

- Initial drug of choice: acetaminophen 4 g/day
- Note patients with hepatic toxicity risk factors, especially those on aspirin. Reassess and taper as tolerated.

Other Pharmacologic Agents

• Nonacetylated salicylate, tramadol, opioids, intra-articular glucocorticoids or hyaluronate, topical capsaicin or methyl salicylate

NSAID Analgesics

- Patients who are not at cardiovascular risk and are not using aspirin
 - Patients at no or low NSALD GL risk:
 - Use a traditional NSAID [A].
 - If GI symptoms develop, add an antacid, H₂ blocker, or proton pump inhibitor (PPI) [A].
 - Patients at NSALD GL risk:
 - Use traditional NSAID plus PPI.
 - Consider non-NSAID therapy.
- Patients who are at cardiovascular risk (consider aspirin)
 - Patients at no or low NSALD GL risk:
 - Use traditional NSAID plus PPI if GI risk warrants gastroprotection [A].
 - Consider non-NSAID therapy
 - Patients at NSALD GL risk:
 - A gastroprotective agent must be added if a traditional NSAID is prescribed.
 - Consider non-NSAID therapy.

Definitions:

Levels of Evidence for the Most Significant Recommendation

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational studies
- D. Opinion of expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is provided for the most significant recommendations (See "Major Recommendations" field).

This guideline is based on the following sources: The 2000 American College of Rheumatology Subcommittee on Osteoarthritis Guidelines: Recommendations for the Medical Management of Osteoarthritis of the Hip and Knee (www.rheumatology.org) and Fendrick A. Mark, Cox-2 Inhibitor use After Vioxx: Careful Balance or End of the Rope? The American Journal of Managed Care, November 2004 (www.ajmc.com).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Through a collaborative approach to developing and implementing common clinical practice guidelines and performance measures for osteoarthritis, Michigan health plans will achieve consistent delivery of evidence-based services and better health outcomes. This approach also will augment the practice environment for physicians by reducing the administrative burdens imposed by compliance with diverse health plan guidelines and associated requirements.

POTENTI AL HARMS

Caution should be exercised in patients with gastrointestinal (GI) risk taking non-steroidal anti-inflammatory drugs (NSAIDs).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline lists core management steps. Individual patient considerations and advances in medical science may supersede or modify these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

When consensus is reached on a final version of the guideline, a statewide mailing of the approved guideline is completed. The guideline is distributed to physicians in the following medical specialties:

- Family Practice
- General Practice
- Internal Medicine

• Other Specialists for which the guideline is applicable (e.g., endocrinologists, allergists, pediatricians, cardiologists)

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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DATE RELEASED

2003 Aug (revised 2005 Aug)

GUIDELINE DEVELOPER(S)

Michigan Quality Improvement Consortium

SOURCE(S) OF FUNDING

Michigan Quality Improvement Consortium

GUI DELI NE COMMITTEE

Michigan Quality Improvement Consortium Medical Director's Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Physician representatives from participating Michigan Quality Improvement Consortium health plans, Michigan State Medical Society, Michigan Osteopathic Association, Michigan Association of Health Plans, Michigan Department of Community Health and Michigan Peer Review Organization

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Michigan Quality Improvement Consortium. Medical management of adults with osteoarthritis. Southfield (MI): Michigan Quality Improvement Consortium; 2003 Aug. 1 p.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Michigan</u> Quality Improvement Consortium Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 14, 2004. The information was verified by the guideline developer on July 27, 2004. This summary was updated by ECRI on January 12, 2005 following the release of a public health advisory from the U.S. Food and Drug Administration regarding the use of some non-steroidal anti-inflammatory drug products. This summary was updated on April 15, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This NGC summary was updated by ECRI on November 28, 2005. The updated information was verified by the guideline developer on December 19, 2005.

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